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12      *C. R. Bard, Inc. and*  
12      *Bard Peripheral Vascular, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA**

17 IN RE: Bard IVC Filters Products Liability Litigation MDL NO. 15-02641-PHX-DGC

**18 | This Document Relates to:**

19 KEVIN GROSS,

**Plaintiff,**

Case No. CV-15-2096-PHX-DGC

21 || v.

22 C. R. BARD, INC., a New Jersey  
23 Corporation; and BARD PERIPHERAL  
VASCULAR INC., an Arizona  
Corporation.

# **DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S ANSWER AND AFFIRMATIVE DEFENSES**

### Defendants.

26 Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”)  
27 (collectively “Defendants”) hereby file their answer and defenses to the Plaintiff’s Complaint  
28 for Damages (the “Plaintiff’s Complaint”) as follows:

## **PARTIES**

1. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding the citizenship and residency of Plaintiff Kevin Gross and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 1 of Plaintiff's Complaint.

2. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff Kevin Gross and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 2 of Plaintiff's Complaint.

3. Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 3 of Plaintiff's Complaint and, on that basis, deny them.

4. Defendants deny the allegations contained in paragraph 4 of Plaintiff's Complaint.

5. Defendants admit that Bard is a New Jersey corporation.

6. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that Bard does business in the State of Pennsylvania. Defendants deny any remaining allegations contained in Paragraph 6 of Plaintiff's Complaint.

7. Defendants admit that BPV is an Arizona Corporation.

8. Defendants admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed IVC filters and that BPV does business in the State of Pennsylvania.

## **JURISDICTION AND VENUE**

9. Defendants do not contest that the injuries and damages alleged within Plaintiff's Complaint exceed the jurisdictional minimum of this Court. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has

1 suffered any damages whatsoever. Defendants do not dispute that, based on the facts as  
2 alleged by Plaintiff, which have not been and could not have been confirmed by Defendants,  
3 jurisdiction appears to be proper in the United States District Court for the Eastern District of  
4 Pennsylvania.

5        10. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which  
6 have not been and could not have been confirmed by Defendants, venue appears to be proper  
7 in the United States District Court for the Eastern District of Pennsylvania. Defendants admit  
8 that they are authorized to do business, and do business, in the State of Pennsylvania,  
9 including this judicial district. Defendants lack knowledge or information sufficient to form a  
10 belief as to the truth of the allegations regarding the trade name of any inferior vena cava  
11 filter implanted in Plaintiff Kevin Gross and, on that basis, deny them.

12        11. Defendants admit that the Judicial Panel of Multidistrict Litigation recently  
13 consolidated certain claims related to Bard IVC filters into MDL No. 2461, the venue for  
14 which is the United States District Court for the District of Arizona and over which Judge  
15 David Campbell presides. Defendants do not dispute that this case should be conditionally  
16 transferred to MDL No. 2461, to be remanded back to the United States District Court for the  
17 Eastern District of Pennsylvania at a later date.

## **GENERAL FACTUAL ALLEGATIONS**

19       12. Defendants lack knowledge or information sufficient to form a belief as to the  
20 truth of the allegations regarding the trade name of any inferior vena cava filter implanted in  
21 Plaintiff Kevin Gross and, on that basis, deny them. Defendants deny the remaining  
22 allegations contained in Paragraph 12 of Plaintiff's Complaint.

23       13. Defendants admit that Bard owns a facility where vena cava filters are  
24 manufactured. Defendants further admit that BPV designs, sells, markets, and distributes  
25 inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters  
26 under the trademark G2® Filter Systems, including in the state of Pennsylvania. Defendants  
27 further admit that inferior vena cava filters are intended to prevent injury or death resulting

1 from venous thrombosis and pulmonary embolism. Defendants are without knowledge or  
2 information sufficient to form a belief as to the truth of the remainder of the allegations  
3 contained in Paragraph 13 of Plaintiff's Complaint and, on that basis, denies them.

4 14. Defendants deny the allegations contained in Paragraph 14 of Plaintiff's  
5 Complaint, including all sub-parts thereof.

6 15. Defendants lack knowledge or information sufficient to form a belief as to the  
7 truth of the allegation regarding the time frame when inferior vena cava filters were first  
8 introduced on the market or the identity of manufacturers of inferior vena cava filters.  
9 Defendants deny any remaining allegations of Paragraph 15 of Plaintiff's Complaint.

10 16. Defendants admit that inferior vena cava filters are intended to prevent injury or  
11 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit  
12 that inferior vena cava filters may be designed for permanent placement, temporary  
13 placement, or both. Defendants deny any remaining allegations of Paragraph 16 of Plaintiff's  
14 Complaint.

15 17. Defendants admit that the inferior vena cava is a large vein that receives blood  
16 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants  
17 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to  
18 human health, including sometimes death. Defendants deny any remaining allegations of  
19 Paragraph 17 of Plaintiff's Complaint.

20 18. Defendants admit that certain people are at an increased risk for the  
21 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information  
22 to form a belief as to the truth of the allegations as stated regarding the various risk factors  
23 which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus  
24 deny them. Defendants deny any remaining allegations of Paragraph 18 of Plaintiff's  
25 Complaint.

26 19. Defendants admit that patients at a high risk for developing deep vein  
27 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,  
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1 including but not limited to the medications listed in Paragraph 19 of Plaintiff's Complaint.  
2 Defendants further admit that inferior vena cava filters may also be used to treat patients who  
3 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants  
4 lack knowledge or information sufficient to form a belief as to the truth of any remaining  
5 allegations contained in Paragraph 19 of Plaintiff's Complaint and, on that basis, deny them.

6       20. Defendants lack knowledge or information sufficient to form a belief as to the  
7 truth of the allegation regarding the time frame when inferior vena cava filters were first  
8 introduced on the market. Defendants also lack knowledge or information sufficient to form a  
9 belief as to the truth of the allegation regarding the time frame when optional or retrievable  
10 filters came to be marketed or the other allegations regarding optional or retrievable filters  
11 marketed by other manufacturers. Defendants admit that the Recovery® Filter System and  
12 the subsequent G2® Filter were cleared by the FDA for optional use as retrievable inferior  
13 vena cava filters. Defendants deny any remaining allegations contained in paragraph 20 of  
14 Plaintiff's Complaint.

15       21. Defendants admit that the Recovery® Filter was cleared by the FDA for  
16 permanent placement on November 27, 2002, pursuant to an application submitted under  
17 Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining  
18 allegations contained in Paragraph 21 of Plaintiff's Complaint, including the allegations  
19 contained in Footnote 1.

20       22. Defendants admit that the Recovery® Filter was cleared by the FDA for  
21 permanent placement on November 27, 2002, pursuant to an application submitted under  
22 Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the  
23 requirements of Section 510(k) are legal conclusions of law to which no answer is required.  
24 Defendants deny any remaining allegations contained in Paragraph 22 of Plaintiff's  
25 Complaint

26       23. Defendants admit that the Recovery® Filter was cleared by the FDA for  
27 retrievable placement on July 25, 2003, pursuant to an application submitted under Section  
28

1 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations  
2 contained in Paragraph 23 of Plaintiff's Complaint.

3 24. Defendants deny the allegations contained in Paragraph 24 of Plaintiff's  
4 Complaint.

5 25. Defendants admit that the Recovery® Filter consists of twelve, shape-memory  
6 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the  
7 twelve wires form two levels of filtration for emboli: the legs provide the lower level of  
8 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining  
9 allegations contained in Paragraph 25 of Plaintiff's Complaint.

10 26. Defendants admit that a nickel-titanium alloy named Nitinol is used in the  
11 manufacture of the Recovery Filter and further admit that Nitinol contains shape memory.  
12 However, to the extent Paragraph 26 purports to cast liability either directly or indirectly  
13 upon Defendants, said Paragraph is expressly denied.

14 27. Defendants admit that the Recovery® Filter was designed to be inserted  
15 endovascularly. Defendants further admit that the Recovery® Filter is designed to be  
16 delivered via an introducer sheath, which is included in the delivery system for the device.  
17 Defendants deny any remaining allegations of Paragraph 27 of Plaintiff's Complaint.

18 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's  
19 Complaint.

20 29. Defendants deny the allegations contained in Paragraph 29 of Plaintiff's  
21 Complaint.

22 30. Defendants deny the allegations contained in Paragraph 30 of Plaintiff's  
23 Complaint.

24 31. Defendants admit that there are various well-documented complications that  
25 may occur as a result of the fracture and/or migration of any inferior vena cava filter.  
26 Defendants further admit that it is well documented that many instances of filter fracture  
27 and/or migration result in no complications whatsoever but, rather, are completely  
28

1 asymptomatic. By way of further response, Bard states that there are incidents related to the  
2 occurrence of known complications associated with every manufacturer of inferior vena cava  
3 filters. Defendants deny any remaining allegations of Paragraph 31 of Plaintiff's Complaint.

4       32. Defendants deny the allegations contained in Paragraph 32 of Plaintiff's  
5 Complaint.

6       33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's  
7 Complaint.

8       34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's  
9 Complaint.

10       35. Defendants admit that there are various well-documented complications that  
11 may occur as a result of the fracture, migration, tilting, or perforation of any inferior vena  
12 cava filter. Defendants further admit that it is well documented that many instances of filter  
13 fracture, migration, tilting, or perforation result in no complications whatsoever but, rather,  
14 are completely asymptomatic. By way of further response, Bard states that there are incidents  
15 related to the occurrence of known complications associated with every manufacturer of  
16 inferior vena cava filters. Defendants deny any remaining allegations of Paragraph 35 of  
17 Plaintiff's Complaint, including all sub-parts thereof.

18       36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's  
19 Complaint.

20       37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's  
21 Complaint.

22       38. Defendants admit that, as part of their continuing efforts to constantly evaluate  
23 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are  
24 continually striving to improve the life-saving performance of those devices. The G2® Filter  
25 was developed in furtherance of those efforts. Defendants deny any remaining allegations  
26 contained in Paragraph 38 of Plaintiff's Complaint.

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1       39. Defendants admit that the G2® Filter was cleared by the FDA pursuant to an  
2 application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants  
3 deny any remaining allegations contained in Paragraph 39 of Plaintiff's Complaint.

4       40. Defendants deny the allegations contained in Paragraph 40 of Plaintiff's  
5 Complaint.

6       41. Defendants deny the allegations contained in Paragraph 41 of Plaintiff's  
7 Complaint.

8       42. Defendants deny the allegations contained in Paragraph 42 of Plaintiff's  
9 Complaint.

10      43. Defendants admit that there are various well-documented complications that  
11 may occur as a result of the fracture, migration, tilting, or perforation of any inferior vena  
12 cava filter. Defendants further admit that it is well documented that many instances of filter  
13 fracture, migration, tilting, or perforation result in no complications whatsoever but, rather,  
14 are completely asymptomatic. By way of further response, Bard states that there are incidents  
15 related to the occurrence of known complications associated with every manufacturer of  
16 inferior vena cava filters. Defendants deny any remaining allegations of Paragraph 43 of  
17 Plaintiff's Complaint, including all sub-parts thereof.

18      44. Defendants state that information available in the public domain, including the  
19 FDA MAUDE database, is not a comprehensive analysis of all instances of such  
20 complications. Defendants deny any remaining allegations of Paragraph 44 of Plaintiff's  
21 Complaint.

22      45. Defendants admit that there are various well-documented complications that  
23 may occur as the result of the fracture and/or migration of any inferior vena cava filter.  
24 Defendants state that there are incidents related to the occurrence of known complications  
25 associated with every manufacturer of inferior vena cava filters. By way of further response,  
26 Defendants state that information available in the public domain, including the FDA MAUDE

1 database, is not a comprehensive analysis of all instances of such complications. Defendants  
2 deny any remaining allegations of Paragraph 45 of Plaintiff's Complaint.

3 46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's  
4 Complaint.

5 47. Defendants deny the allegations contained in Paragraph 47 of Plaintiff's  
6 Complaint.

7 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's  
8 Complaint.

9 49. Defendants deny the allegations contained in Paragraph 49 of Plaintiff's  
10 Complaint, including all sub-parts thereof.

11 50. Defendants deny the allegations contained in Paragraph 50 of Plaintiff's  
12 Complaint.

13 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's  
14 Complaint.

15 **SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF**

16 52. Defendants are without knowledge or information sufficient to form a belief as  
17 to the truth of the allegations contained in Paragraph 52 of Plaintiff's Complaint and, on that  
18 basis, deny them.

19 53. Defendants are without knowledge or information sufficient to form a belief as  
20 to the truth of the allegations regarding the trade name of any inferior vena cava filter  
21 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining  
22 allegations of Paragraph 53 of Plaintiff's Complaint.

23 54. Defendants deny the allegations contained in Paragraph 54 of Plaintiff's  
24 Complaint.

25 55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's  
26 Complaint.

## **FRAUDULENT CONCEALMENT**

56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's Complaint.

57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's Complaint.

58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's Complaint.

59. Defendants deny the allegations contained in Paragraph 59 of Plaintiff's Complaint.

## **CORPORATE/VICARIOUS LIABILITY**

60. Defendants deny the allegations contained in Paragraph 60 of Plaintiff's Complaint.

61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's Complaint.

62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's Complaint.

63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's Complaint.

## **FIRST CAUSE OF ACTION**

## **NEGLIGENCE**

64. Defendants incorporate by reference their responses to Paragraphs 1-63 of Plaintiff's Complaint as if fully set forth herein.

65. Defendants deny the allegations of Paragraph 65 of Plaintiff's Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery® and G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and

1 distributed filters under the trademarks Recovery® and G2® Filter Systems. Defendants  
2 deny any remaining allegations contained in Paragraph 65 of Plaintiff's Complaint.

3       66. Defendants are without knowledge or information sufficient to form a belief as  
4 to the truth of the allegations regarding the trade name of any inferior vena cava filter  
5 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining  
6 allegations of Paragraph 66 of Plaintiff's Complaint.

7       67. The allegations contained in Paragraph 67 of Plaintiff's Complaint regarding  
8 Defendants' duty are legal conclusions of law, and no answer is required. To the extent a  
9 response is required, Defendants deny the allegations. Defendants deny the remaining  
10 allegations contained in Paragraph 67 of Plaintiff's Complaint.

11       68. Defendants deny the allegations contained in Paragraph 68 of Plaintiff's  
12 Complaint.

13       69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's  
14 Complaint, including all sub-parts thereof.

15       70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's  
16 Complaint.

17       71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's  
18 Complaint.

19       72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's  
20 Complaint, including all sub-parts thereof.

21       73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's  
22 Complaint.

23       74. Defendants deny the allegations contained in Paragraph 74 of Plaintiff's  
24 Complaint.

25       75. Defendants deny that they are liable to Plaintiff for any amount whatsoever,  
26 that Plaintiff has suffered any damages whatsoever, and that Plaintiff is entitled to any  
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1 recovery or relief whatsoever. Defendants deny any remaining allegations contained in  
2 Paragraph 75 of Plaintiff's Complaint.

3 **SECOND CAUSE OF ACTION**

4 **STRICT LIABILITY FAILURE TO WARN**

5 76. Defendants incorporate by reference their responses to Paragraphs 1-75 of  
6 Plaintiff's Complaint as if fully set forth herein.

7 77. Defendants are without knowledge or information sufficient to form a belief as  
8 to the truth of the allegations regarding the trade name of any inferior vena cava filter  
9 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants  
10 admit that Bard owns a facility where vena cava filters are manufactured and that filters under  
11 the trademark G2® Filter System were manufactured at that facility. Defendants further  
12 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV  
13 designed, sold, marketed, and distributed filters under the trademark G2® Filter System.  
14 Defendants deny any remaining allegations contained in Paragraph 77 of Plaintiff's  
15 Complaint.

16 78. Defendants deny the allegations contained in Paragraph 78 of Plaintiff's  
17 Complaint.

18 79. The allegations contained in Paragraph 79 of Plaintiff's Complaint regarding  
19 Defendants' duty are legal conclusions of law, and no answer is required. To the extent a  
20 response is required, Defendants deny the allegations. Defendants deny the remaining  
21 allegations contained in Paragraph 79 of Plaintiff's Complaint.

22 80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's  
23 Complaint.

24 81. Defendants deny the allegations contained in Paragraph 81 of Plaintiff's  
25 Complaint.

26 82. Defendants deny the allegations contained in Paragraph 82 of Plaintiff's  
27 Complaint.

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1           83. Defendants deny the allegations contained in Paragraph 83 of Plaintiff's  
2 Complaint.

3           84. Defendants deny the allegations contained in Paragraph 84 of Plaintiff's  
4 Complaint.

5           85. Defendants deny the allegations contained in Paragraph 85 of Plaintiff's  
6 Complaint.

7        86. Defendants deny the allegations contained in Paragraph 86 of Plaintiff's  
8 Complaint.

9       87. Defendants deny that they are liable to Plaintiff for any amount whatsoever,  
10 that Plaintiff has suffered any damages whatsoever, and that Plaintiff is entitled to any  
11 recovery or relief whatsoever. Defendants deny any remaining allegations contained in  
12 Paragraph 87 of Plaintiff's Complaint.

### **THIRD CAUSE OF ACTION**

## **STRICT LIABILITY DESIGN DEFECTS**

15           88. Defendants incorporate by reference their responses to Paragraphs 1-87 of  
16 Plaintiff's Complaint as if fully set forth herein.

17        89. Defendants are without knowledge or information sufficient to form a belief as  
18 to the truth of the allegations regarding the trade name of any inferior vena cava filter  
19 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants  
20 admit that Bard owns a facility where vena cava filters are manufactured. Defendants further  
21 admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants  
22 deny any remaining allegations contained in Paragraph 89 of Plaintiff's Complaint.

23 90. Defendants deny the allegations contained in Paragraph 90 of Plaintiff's  
24 Complaint.

25           91. Defendants deny the allegations contained in Paragraph 91 of Plaintiff's  
26 Complaint.

1           92. Defendants deny the allegations contained in Paragraph 92 of Plaintiff's  
2 Complaint.

3           93. Defendants deny the allegations contained in Paragraph 93 of Plaintiff's  
4 Complaint.

5           94. Defendants deny the allegations contained in Paragraph 94 of Plaintiff's  
6 Complaint.

7           95. Defendants deny the allegations contained in Paragraph 95 of Plaintiff's  
8 Complaint.

9       96. Defendants deny that they are liable to Plaintiff for any amount whatsoever,  
10 that Plaintiff has suffered any damages whatsoever, and that Plaintiff is entitled to any  
11 recovery or relief whatsoever. Defendants deny any remaining allegations contained in  
12 Paragraph 96 of Plaintiff's Complaint.

## **FOURTH CAUSE OF ACTION**

## **STRICT LIABILITY MANUFACTURING DEFECT**

15        97. Defendants incorporate by reference their responses to Paragraphs 1-96 of  
16 Plaintiff's Complaint as if fully set forth herein.

17       98. Defendants are without knowledge or information sufficient to form a belief as  
18 to the truth of the allegations regarding the trade name of any inferior vena cava filter  
19 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants  
20 admit that Bard owns a facility where vena cava filters are manufactured. Defendants further  
21 admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants  
22 deny any remaining allegations contained in Paragraph 98 of Plaintiff's Complaint.

23        99. Defendants deny the allegations contained in Paragraph 99 of Plaintiff's  
24 Complaint.

25       100. Defendants deny the allegations contained in Paragraph 100 of Plaintiff's  
26 Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of Plaintiff's Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiff's Complaint.

103. Defendants deny that they are liable to Plaintiff for any amount whatsoever, that Plaintiff has suffered any damages whatsoever, and that Plaintiff is entitled to any recovery or relief whatsoever. Defendants deny any remaining allegations contained in Paragraph 103 of Plaintiff's Complaint.

## **FIFTH CAUSE OF ACTION**

## **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

104. Defendants incorporate by reference their responses to Paragraphs 1-103 of Plaintiff's Complaint as if fully set forth herein.

105. Defendants deny the allegations contained in Paragraph 105 of Plaintiff's Complaint.

106. Defendants deny the allegations contained in Paragraph 106 of Plaintiff's Complaint.

107. Defendants deny the allegations contained in Paragraph 107 of Plaintiff's Complaint.

108. Defendants deny the allegations contained in Paragraph 108 of Plaintiff's Complaint.

109. Defendants deny the allegations contained in Paragraph 109 of Plaintiff's Complaint, including all subparts thereof.

110. Defendants deny the allegations contained in Paragraph 110 of Plaintiff's Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of Plaintiff's Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's Complaint.

113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff's Complaint.

114. Defendants deny that they are liable to Plaintiff for any amount whatsoever, that Plaintiff has suffered any damages whatsoever, and that Plaintiff is entitled to any recovery or relief whatsoever. Defendants deny any remaining allegations contained in Paragraph 114 of Plaintiff's Complaint.

## **SIXTH CAUSE OF ACTION**

## **NEGIGENT MISREPRESENTATION**

115. Defendants incorporate by reference their responses to Paragraphs 1-114 of Plaintiff's Complaint as if fully set forth herein.

116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's Complaint, including all sub-parts thereof.

117. Defendants deny the allegations contained in Paragraph 117 of Plaintiff's Complaint.

118. Defendants deny the allegations contained in Paragraph 118 of Plaintiff's Complaint.

119. Defendants deny the allegations contained in Paragraph 119 of Plaintiff's Complaint.

120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of Plaintiff's Complaint.

122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's Complaint.

123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's Complaint.

124. Defendants deny the allegations contained in Paragraph 124 of Plaintiff's Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's Complaint.

126. Defendants deny that they are liable to Plaintiff for any amount whatsoever, that Plaintiff has suffered any damages whatsoever, and that Plaintiff is entitled to any recovery or relief whatsoever. Defendants deny any remaining allegations contained in Paragraph 126 of Plaintiff's Complaint.

## **SEVENTH CAUSE OF ACTION**

## PUNITIVE DAMAGES

127. Defendants incorporate by reference their responses to Paragraphs 1-126 of Plaintiff's Complaint as if fully set forth herein.

128. Defendants deny the allegations contained in Paragraph 128 of Plaintiff's Complaint.

129. Defendants deny the allegations contained in Paragraph 129 of Plaintiff's Complaint, including all sub-parts thereof.

130. Defendants deny the allegations contained in Paragraph 130 of Plaintiff's Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiff's Complaint.

132. Defendants deny that they are liable to Plaintiff for any amount whatsoever, that Plaintiff has suffered any damages whatsoever, and that Plaintiff is entitled to any recovery or relief whatsoever. Defendants deny any remaining allegations contained in Paragraph 132 of Plaintiff's Complaint.

1        Furthermore, responding to the unnumbered Paragraph following the heading  
2 “PRAYER FOR RELIEF” and beginning “WHEREFORE,” Defendants deny the allegations  
3 contained in such Paragraph and all sub-parts thereof.

4        Defendants further deny each and every allegation not specifically admitted herein,  
5 including any allegations in paragraph or section headings.

6                          **DEFENSES AND AFFIRMATIVE DEFENSES**

7        Defendants allege as affirmative defenses the following:

8        1.       Plaintiff’s Complaint fails to state a claim or claims upon which relief can be  
9 granted under Pennsylvania law.

10       2.       The sole proximate cause of Plaintiff’s damages, if any were sustained, was the  
11 negligence of a person or persons or entity for whose acts or omissions Defendants were and  
12 are in no way liable.

13       3.       If Plaintiff has been damaged, which Defendants deny, any recovery by  
14 Plaintiff is barred to the extent Plaintiff voluntarily exposed himself to a known risk and/or  
15 failed to mitigate his alleged damages. To the extent Plaintiff has failed to mitigate his  
16 alleged damages, any recovery shall not include alleged damages that could have been  
17 avoided by reasonable care and diligence.

18       4.       Plaintiff failed to exercise ordinary care for his own safety such that Plaintiff is  
19 not entitled to recover.

20       5.       The injuries and damages allegedly sustained by Plaintiff may be due to the  
21 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff  
22 over which Defendants had no control.

23       6.       Plaintiff’s causes of action may be barred by the applicable statute of  
24 limitations and/or statute of repose.

25       7.       Plaintiff’s claims are barred, in whole or in part, by the doctrines of laches,  
26 waiver, and/or estoppel.

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1       8. There was no defect in the product at issue with the result that Plaintiff is not  
2 entitled to recover against Defendants in this cause.

3       9. There was no causal connection between any alleged defect in the product at  
4 issue and Plaintiff's alleged damages with the result that Plaintiff is not entitled to recover  
5 against Defendants in this cause.

6       10. If Plaintiff has been damaged, which Defendants deny, such damages were  
7 caused by the negligence or fault of Plaintiff.

8       11. If Plaintiff has been damaged, which Defendants deny, such damages were  
9 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are  
10 not legally responsible.

11       12. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to  
12 by Plaintiff or other persons or entities that are severally liable for all or part of Plaintiff's  
13 alleged injuries, losses or damages. Defendants will request apportionment of fault.

14       13. Plaintiff's alleged damages, if any, should be apportioned among all parties at  
15 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors  
16 Act.

17       14. In the further alternative, and only in the event that it is determined that  
18 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to  
19 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,  
20 any other defendants, third-party defendants, or other persons, including any party immune  
21 because bankruptcy renders them immune from further litigation, as well as any party, co-  
22 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

23       15. The trier of fact should apportion its award of damages among the persons who  
24 are liable according to the degree of fault of each person.

25       16. If Plaintiff has been damaged, which Defendants deny, the negligence or fault  
26 of Plaintiff constitutes the sole, intervening, and superseding cause of Plaintiff's alleged  
27 damages.

1       17. If Plaintiff has been damaged, which Defendants deny, the negligence or fault  
2 of persons and/or entities for whose conduct Defendants are not legally responsible  
3 constitutes the sole, intervening, and superseding cause of Plaintiff's alleged damages.

4       18. If Plaintiff has been damaged, which Defendants deny, the actions of persons or  
5 entities for whose conduct Defendants are not legally responsible and the independent  
6 knowledge of these persons or entities of the risks inherent in the use of the product and other  
7 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged  
8 damages.

9       19. If Plaintiff has been damaged, which Defendants deny, such damages were  
10 caused by unforeseeable, independent, intervening, and/or superseding events for which  
11 Defendants are not legally responsible.

12       20. If Plaintiff has been damaged, which Defendants deny, such damages were  
13 caused by abuse, misuse, user error and/or modification of the product at issue for which  
14 Defendants were and are in no way liable.

15       21. Defendants made no warranties of any kind, express or implied, including any  
16 alleged implied warranty of merchantability or implied warranty of fitness for a particular  
17 purpose, or any representations of any nature whatsoever to Plaintiff. To the extent  
18 applicable, Plaintiff's breach of warranty claims are barred by a lack of privity between  
19 Plaintiff and Defendants. Plaintiff's implied warranty claims are barred or limited by any and  
20 all express conditions or disclaimers, by Plaintiff's lack of reliance on any such warranties,  
21 and by waiver.

22       22. Plaintiff's claims for breach of implied warranty must fail because the product  
23 was not used for its ordinary purpose.

24       23. Plaintiff's claim for breach of warranty is barred because Plaintiff did not first  
25 give notice of any alleged defect of the product to Defendants.

26       24. Defendants neither had nor breached any alleged duty to warn with respect to  
27 the product, with the result that Plaintiff is not entitled to recover in this cause.

1       25. Plaintiff's failure to warn claims are barred by virtue of the intervention of the  
2 learned intermediary or intermediaries to whom Defendants discharged their duties to warn.

3       26. The conduct of Defendants and the subject product at all times conformed with  
4 the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and  
5 regulations. Accordingly, Plaintiff's claims are barred, in whole or in part, under the doctrine  
6 of federal preemption, and granting the relief requested would impermissibly infringe upon  
7 and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause  
8 of the United States Constitution.

9       27. If Plaintiff recovers from Defendants, Defendants are entitled to contribution,  
10 set-off, and/or indemnification, either in whole or in part, from all persons or entities whose  
11 negligence or fault proximately caused or contributed to cause Plaintiff's alleged damages.

12       28. Plaintiff's claims are or may be barred, in whole or in part, to the extent that  
13 Plaintiff has released, settled with, entered into an accord and satisfaction, or otherwise  
14 compromised her claims. Defendants are entitled to a set-off for the entire amount of  
15 proceeds Plaintiff has or may recover from all other sources.

16       29. Should Defendants be held liable to Plaintiff, which liability is specifically  
17 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff  
18 from all collateral sources.

19       30. Defendants assert any and all defenses, claims, credits, offsets, or remedies  
20 provided by the Restatements (Second and Third) of Torts and reserve the right to amend  
21 their Answer to file such further pleadings as are necessary to preserve and assert such  
22 defenses, claims, credits, offsets, or remedies.

23       31. The device at issue was not sold in a defective condition unreasonably  
24 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the  
25 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and  
26 comparable provisions of the Restatement (Third) of Torts (Products Liability).

1       32. Plaintiff's claims are barred because the methods, standards, warnings, and  
2 instructions used in manufacturing and/or marketing the product at issue conformed with the  
3 generally recognized, reasonably available, and reliable state of knowledge when the product  
4 was manufactured and marketed.

5       33. Plaintiff's claims are barred because the methods, standards, warnings, and  
6 instructions used in manufacturing and/or marketing the product at issue conformed to  
7 industry custom/usage standards and/or legislative, administrative, and/or regulatory  
8 standards.

9       34. At all relevant times during which the device at issue was designed, developed,  
10 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended  
11 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,  
12 information, and instructions, all pursuant to generally recognized prevailing industry  
13 standards and state-of-the-art in existence at the time.

14       35. The design complained of in Plaintiff's Complaint, the alleged defects of the  
15 product, and/or any alternative design claimed by Plaintiff were not known and, in light of the  
16 existing, reasonably-available scientific and technological knowledge, could not have been  
17 known at the time the product at issue was designed, manufactured, and sold. Any alleged  
18 alternative design was not scientifically or technologically feasible or economically practical.

19       36. Defendants specifically plead all affirmative defenses under the Uniform  
20 Commercial Code ("UCC") now existing or which may arise in the future, including those  
21 defenses provided by UCC §§ 2-607 and 2-709.

22       37. No act or omission of Defendants was malicious, willful, wanton, reckless, or  
23 grossly negligent, and, therefore, any award of punitive damages is barred.

24       38. To the extent Plaintiff asserts a demand for punitive damages, Defendants  
25 specifically incorporate by reference any and all standards of limitations regarding the  
26 determination and/or enforceability of punitive damages awards that arose in the decisions of  
27 *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman*  
28

1      *Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.  
2      1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.  
3      June 25, 2008) and their progeny as well as other similar cases under both federal and state  
4      law.

5            39. Plaintiff's claim for punitive damages is in contravention of the rights of  
6      Defendants under the following provisions of the United States Constitution and analogous  
7      provisions of the Pennsylvania Constitution:

8            Plaintiff's claims for punitive or exemplary damages violate, and are therefore barred  
9      by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the  
10     United States of America on grounds including the following:

- 11        (a) it is a violation of the Due Process and Equal Protection Clauses of the  
12        Fourteenth Amendment of the United States Constitution to impose punitive  
13        damages, which are penal in nature, against a civil defendant upon the plaintiffs  
14        satisfying a burden of proof which is less than the "beyond a reasonable doubt"  
15        burden of proof required in criminal cases;
- 16        (b) the procedures pursuant to which punitive damages are awarded may result in  
17        the award of joint and several judgments against multiple defendants for  
18        different alleged acts of wrongdoing, which infringes upon the Due Process and  
19        Equal Protection Clauses of the Fourteenth Amendment of the United States  
20        Constitution;
- 21        (c) the procedures to which punitive damages are awarded fail to provide a  
22        reasonable limit on the amount of the award against defendant, which thereby  
23        violates the Due Process Clause of the Fourteenth Amendment of the United  
24        States Constitution;
- 25        (d) the procedures pursuant to which punitive damages are awarded fail to provide  
26        specific standards for the amount of the award of punitive damages which

1           thereby violates the Due Process Clause of the Fourteenth Amendment of the  
2           United States Constitution;

3           (e) the procedures pursuant to which punitive damages are awarded result in the  
4           imposition of different penalties for the same or similar acts, and thus violate  
5           the Equal Protection Clause of the Fourteenth Amendment of the United States  
6           Constitution;

7           (f) the procedures pursuant to which punitive damages are awarded permit the  
8           imposition of punitive damages in excess of the maximum criminal fine for the  
9           same or similar conduct, which thereby infringes upon the Due Process Clause  
10          of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the  
11          Fourteenth Amendment of the United States Constitution;

12          (g) the procedures pursuant to which punitive damages are awarded permit the  
13          imposition of excessive fines in violation of the Eighth Amendment of the  
14          United States Constitution;

15          (h) the award of punitive damages to the plaintiffs in this action would constitute a  
16          deprivation of property without due process of law; and

17          (i) the procedures pursuant to which punitive damages are awarded permit the  
18          imposition of an excessive fine and penalty.

19          40. This case may be subject to dismissal or transfer under the doctrine of forum  
20          non conveniens.

21          41. The device at issue complied with any applicable product safety statute or  
22          administrative regulation, and therefore Plaintiff's defective design and warnings-based  
23          claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and  
24          comments thereof.

25          42. Defendants reserve the right to raise such other affirmative defenses as may be  
26          available or apparent during discovery or as may be raised or asserted by other defendants in  
27          this case. Defendants have not knowingly or intentionally waived any applicable affirmative

1 defense. If it appears that any affirmative defense is or may be applicable after Defendants  
2 have had the opportunity to conduct reasonable discovery in this matter, Defendants will  
3 assert such affirmative defense. Defendants intend to rely upon any additional defenses under  
4 Pennsylvania law that become available during the course of investigation and/or discovery  
5 and reserves the right to amend its Answer to assert these defenses.

6 **REQUEST FOR JURY TRIAL**

7 Defendants seek a trial by jury on all issues so triable.

8 **WHEREFORE**, Defendants state that Plaintiff is not entitled to the relief demanded  
9 in Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action  
10 against them be dismissed and that they be awarded their costs in defending this action and  
11 that they be granted such other and further relief as the Court deems just and appropriate.

12 This 20th day of October, 2015.

13 s/Richard B. North, Jr.  
14 Richard B. North, Jr.

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23  
24 **Attorney for Defendants C. R. Bard, Inc. and**  
**Bard Peripheral Vascular, Inc.**  
25  
26  
27  
28

1                   **CERTIFICATE OF SERVICE**  
2  
3

4                   I HEREBY CERTIFY that on October 20, 2015, I electronically filed the foregoing  
5 with the Clerk of the Court by using the CM/ECF system which will send notification of such  
6 filing to all counsel of record.

7                   s/Richard B. North, Jr.  
8                   Richard B. North, Jr.  
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